UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,428	06/28/2004	Eiji Sugaru	229576	7677

23460 7590 01/20/2006

LEYDIG VOIT & MAYER, LTD
TWO PRUDENTIAL PLAZA, SUITE 4900
180 NORTH STETSON AVENUE
CHICAGO, IL 60601-6780

EXAMINER	
DOWELL, PAUL THOMAS	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 01/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/500,428	SUGARU ET AL.	
	Examiner	Art Unit	
	Paul Dowell	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-40 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 2, 4, 6, drawn to a therapeutic agent for cibophobia comprising a substance that suppresses expression or function of a polypeptide, said polypeptide consisting of an amino acid sequence of SEQ ID NO:2 or SEQ ID NO:4, wherein said therapeutic agent comprises:

(a) a nucleic acid consisting of a base sequence complementary to a base sequence shown in SEQ ID NO:1 or SEQ ID NO: 3; or

(b) a nucleic acid consisting of a base sequence capable of hybridizing with a nucleic acid consisting of a base sequence shown in SEQ ID NO:1 or SEQ ID NO:3,

and which is capable of inhibiting translation into a polypeptide encoded by the base sequence shown in SEQ ID NO:1 or SEQ ID NO:3 in a hybridized state; and an expression vector comprising the nucleic acid of **(a)** or **(b)**.

Group II, claim(s) 2, 4, 6, 7, drawn to a therapeutic agent for cibophobia comprising a substance that suppresses expression or function of a polypeptide, said polypeptide consisting of an amino acid sequence of SEQ ID NO:2 or SEQ ID NO:4, wherein said therapeutic agent comprises a host cell transfected with an expression vector encoding:

(a) a nucleic acid consisting of a base sequence complementary to a base sequence shown in SEQ ID NO:1 or SEQ ID NO: 3; or

(b) a nucleic acid consisting of a base sequence capable of hybridizing with a nucleic acid consisting of a base sequence shown in SEQ ID NO:1 or SEQ ID NO:3,

and which is capable of inhibiting translation into a polypeptide encoded by the base sequence shown in SEQ ID NO:1 or SEQ ID NO:3 in a hybridized state. Claims 2, 4, 6 are included in group II to the extent that they read on an expression vector encoding **(a)** or **(b)**, the vector being transfected into a host cell and the transfected host cell being the therapeutic agent of group II.

Group III, claim(s) 3, 5, drawn to a therapeutic agent for cibophobia comprising a substance that suppresses expression or function of a polypeptide, said polypeptide consisting of an amino acid sequence of SEQ ID NO:2 or SEQ ID NO:4, wherein said therapeutic agent comprises a substance which shows a specific affinity for a polypeptide, said polypeptide consisting of an amino acid sequence shown in SEQ ID NO:2 or SEQ ID NO:4, and which inhibits expression of said polypeptide.

Claim 1 link(s) the inventions of groups I-III. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Upon election of **groups I or II**, Applicant's are required to further elect one nucleic acid from the group consisting of SEQ ID NO:1 (encoding the polypeptide of SEQ ID NO:2) and SEQ ID NO:3 (encoding the polypeptide of SEQ ID NO:4). Upon election of **group III**, Applicant's are required to further elect one polypeptide from the group consisting of SEQ ID NO:2 and SEQ ID NO:4. It is noted that this is a restriction requirement and not a species election since the nucleic acids of SEQ ID NO:1 and 3 and the polypeptides of SEQ ID NO:2 and 4 have distinct structure.

Group IV, claim(s) 9, 12, drawn to a therapeutic agent for a lifestyle-related disease comprising a substance that enhances expression or function of a polypeptide, said polypeptide consisting of an amino acid sequence shown in SEQ ID NO:2 or SEQ ID NO:4., wherein said therapeutic agent comprises:

(a) a polypeptide consisting of an amino acid sequence shown in SEQ ID NO:2 or SEQ ID NO:4,

(b) a polypeptide consisting of an amino acid shown in SEQ ID NO:2 or SEQ ID NO:4; wherein one or more amino acids of the amino acid sequence of SEQ ID NO:2 or SEQ ID NO:4 have been substituted, deleted, inserted added or modified; wherein said polypeptide shows a ligand-receptor interaction of the same level as the polypeptide of (a); wherein said polypeptide is coupled with a G protein α subunit and when coupled with said G protein α subunit shows an activity to promote a GDP/GTP exchange reaction of said subunit, or

(c) a polypeptide which is an ortholog of the polypeptide of (a).

Group V, claim(s) 9, 10, 12, drawn to a therapeutic agent for a lifestyle-related disease comprising a substance that enhances expression or function of a polypeptide, said polypeptide consisting of an amino acid sequence shown in SEQ ID NO:2 or SEQ ID NO:4., wherein said therapeutic agent comprises an expression vector encoding:

(a) a polypeptide consisting of an amino acid sequence shown in SEQ ID NO:2 or SEQ ID NO:4,

(b) a polypeptide consisting of an amino acid shown in SEQ ID NO:2 or SEQ ID NO:4; wherein one or more amino acids of the amino acid sequence of SEQ ID NO:2 or SEQ ID NO:4 have been substituted, deleted, inserted added or modified; wherein said polypeptide shows a ligand-receptor interaction of the same level as the polypeptide of (a); wherein said polypeptide is coupled with a G protein α subunit and when coupled with said G protein α subunit shows an activity to promote a GDP/GTP exchange reaction of said subunit, or

(c) a polypeptide which is an ortholog of the polypeptide of (a).

Claim 9 is included in group V to the extent that claim 9 reads on a polypeptide of **(a)**, **(b)** or **(c)** encoded by an expression vector, the expression vector being the therapeutic agent of group V.

Group VI, claim(s) 9, 10, 11, 12, drawn to a therapeutic agent for a lifestyle-related disease comprising a substance that enhances expression or function of a polypeptide, said polypeptide consisting of an amino acid sequence shown in SEQ ID NO:2 or SEQ ID NO:4., wherein said therapeutic agent comprises a host cell transfected with an expression vector encoding:

(a) a polypeptide consisting of an amino acid sequence shown in SEQ ID NO:2 or SEQ ID NO:4,

(b) a polypeptide consisting of an amino acid shown in SEQ ID NO:2 or SEQ ID NO:4; wherein one or more amino acids of the amino acid sequence of SEQ ID NO:2 or SEQ ID NO:4 have been substituted, deleted, inserted added or modified; wherein said polypeptide shows a ligand-receptor interaction of the same level as the polypeptide of (a); wherein said polypeptide is coupled with a G protein α subunit and when coupled with said G protein α subunit shows an activity to promote a GDP/GTP exchange reaction of said subunit, or

(c) a polypeptide which is an ortholog of the polypeptide of (a).

Claims 9 and 10 are included in group VI to the extent that they read on a polypeptide of **(a)**, **(b)** or **(c)** encoded by an expression vector, the vector being transfected into a host cell and the transfected host cell being the therapeutic agent of group VI.

Claim 8 link(s) the inventions of groups IV-VI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 8. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Upon election of **groups IV, V or VI**, Applicant's are required to further elect one polypeptide from the group consisting of SEQ ID NO:2 and SEQ ID NO:4. It is noted that this is a restriction requirement and not a species election since the polypeptides of SEQ ID NO:2 and 4 have distinct structure.

Group VII, claim(s) 13-40, drawn to a screening system for a substance having a therapeutic activity against cibophobia or a lifestyle-related disease comprising a lipid bilayer membrane, a method of screening using said screening system and the substance identified by said method; said lipid bilayer membrane of said screening system further comprising:

(a) a polypeptide consisting of an amino acid sequence shown in SEQ ID NO:2 or SEQ ID NO:4, or

(b) a polypeptide consisting of an amino acid shown in SEQ ID NO:2 or SEQ ID NO:4; wherein one or more amino acids of the amino acid sequence of SEQ ID NO:2 or SEQ ID NO:4 have been substituted, deleted, inserted added or modified; wherein said polypeptide shows a ligand-receptor interaction of the

same level as the polypeptide of (a); wherein said polypeptide is coupled with a G protein α subunit and when coupled with said G protein α subunit shows an activity to promote a GDP/GTP exchange reaction of said subunit, or

(c) a polypeptide which is an ortholog of the polypeptide of (a), said polypeptide comprising at least a receptor binding region of a G protein α subunit belonging to a certain family and comprising a guanine nucleotide-binding region of any G protein α subunit;

wherein said screening system is generated by: transfecting a eukaryotic cell with expression vectors encoding said constituent polypeptides and homogenizing the eukaryotic cell transfected with said expression vectors thereby generating a screening system for a substance comprising a lipid bilayer membrane, said lipid bilayer membrane further comprising **(a)**, **(b)** or **(c)**.

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. In the instant case, the technical feature appears to be: **(a)** a nucleic acid consisting of a base sequence complementary to a base sequence shown in SEQ ID NO:1 or SEQ ID NO: 3; or **(b)** a nucleic acid consisting of a base sequence capable of hybridizing with a nucleic acid consisting of a base sequence shown in SEQ ID NO:1 or SEQ ID NO:3. Said technical feature does not link the inventions of groups I-VII. For example, group I is drawn to a therapeutic agent comprising **(a)** a nucleic acid consisting of a base sequence complementary to a base sequence shown in SEQ ID NO:1 or SEQ ID NO: 3; or **(b)** a nucleic acid consisting of a base sequence capable of hybridizing with a nucleic acid consisting of a base sequence shown in SEQ ID NO:1 or SEQ ID NO:3; while group II is drawn to a therapeutic agent comprising a host cell transfected with an expression vector encoding **(a)** a nucleic acid consisting of a base sequence complementary to a base sequence shown in SEQ ID NO:1 or SEQ ID NO: 3; or **(b)** a nucleic acid consisting of a base sequence capable of hybridizing with a nucleic acid consisting of a base sequence shown in SEQ ID NO:1 or SEQ ID NO:3. Therapeutic agents comprising nucleic acids are structurally and functionally distinct from therapeteutic agents

comprising host cells transfected with nucleic acids. Therefore, there does not appear to be a shared same or corresponding technical feature.

Furthermore, while groups I-III are related in being drawn to therapeutic agents that suppress expression or function of a polypeptide of SEQ ID NO:2/4, they are patentably distinct each from the other because groups I-III are drawn to therapeutic agents that have distinct structure and function. For example, group I is drawn to a nucleic acid; while group II is drawn to a host cell transfected with a nucleic acid; while group III is drawn to a substance (e.g. an antibody) that has affinity for a polypeptide of SEQ ID NO:2/4. Nucleic acids, host cells transfected with a nucleic acid and antibodies have distinct structure and function each from the other and therefore groups I-III are distinct.

Furthermore, while groups IV-VI are related in being drawn to therapeutic agents that enhance expression or function of a polypeptide of SEQ ID NO:2/4, they are patentably distinct each from the other because groups IV-VI are drawn to therapeutic agents that have distinct structure and function. For example, group IV is drawn to a polypeptide; while group V is drawn to a nucleic acid; while group VI is drawn to a host cell transfected with a nucleic acid. Polypeptides, nucleic acids and host cells transfected with a nucleic acid have distinct structure and function each from the other and therefore groups IV-VI are distinct.

Furthermore, while groups I-III and groups IV-VI are related in being drawn to therapeutic agents, they are patentably distinct each from the other because they are drawn to therapeutic agents having opposing utilities. Specifically, groups I-III are drawn to therapeutic agents that suppress expression or function of a polypeptide of SEQ ID NO:2/4 while groups IV-VI are drawn to therapeutic agents that enhance expression or function of a polypeptide of SEQ ID NO:2/4. Therapeutic agents that have opposing utilities are distinct and therefore groups I-III and groups IV-VI are distinct each from the other.

Furthermore, while groups I-VI are related to group VII in being drawn to therapeutic agents for cibophobia or a lifestyle-related disease and a screening system for a substance having a therapeutic activity against cibophobia or a lifestyle-related

disease, respectively, they are patentably distinct each from the other because the agents of groups I-VI have different utilities from the screening system of group VII. For example, groups I-VI are drawn to therapeutic agents to be used to treat cibophobia or a lifestyle-related disease while group VII is drawn to a screening system to identify the agents of groups I-VI. Therefore, the inventions of groups I-VII are distinct each from the other.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Dowell whose telephone number is (571)272-5540. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER

Paul Dowell
Art Unit 1632